MAR 1 2 2004

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:

Stryker® Leibinger Universal Distal Radius System

K040002
page 1 of 1

**General Information**

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|---|---|
| Proprietary Name: | Stryker® Leibinger Universal Distal Radius System |
| Common Name: | Small Bone Plating System |
| Proposed Regulatory Class: | Class II |
| Device Classification: | 87HRS (21 CFR 888.3030) Single/Multiple Component Metallic Bone Fixation Appliances and Accessories<br>87LRN (21 CFR 888.3010) Bone Fixation cerclage |
| Submitter: | Stryker Leibinger<br>4100 East Milham Avenue<br>Kalamazoo, MI 49001<br>269-323-4226 |
| Submitter's Registration #: | 1811755 |
| Manufacturer's Registration #: | 8010177 |
| Contact Person: | Wade T. Rutkoskie<br>Associate Manager RA QA<br>Phone: 269-323-4226<br>Fax: 269-323-4215 |
| Summary Preparation Date: | January 5, 2004 |

**Intended Use**

Stryker® Leibinger Universal Distal Radius System is intended for use in internal fixation of the small bone fractures, primarily including distal radius fractures. Examples of these distal radius fractures include but are not limited to compression fractures, intra-articular and extra-articular fractures, displaced fractures and surgical reduction. This system can be used for palmar, dorsal or orthogonal application.

**SUBSTANTIAL EQUIVALENCY INFORMATION**

The Stryker® Leibinger Universal Distal Radius System is substantially equivalent to legally marketed K981283 Rogachefsky Distal Radius Plates, K961496 Radius Reconstruction Plating System, and K014263 Universal Mandible System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2004

Mr. Wade T. Rutkoskie
Associate Manager, Regulatory Affairs and Quality Assurance
Stryker Instruments, Leibinger Division
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K040022
Trade/Device Name: Stryker® Leibinger Universal Distal Radius System
Regulation Numbers: 21 CFR 888.3030, 21 CFR 888.3010
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories, Bone fixation cerclage
Regulatory Class: II
Product Codes: HRS, LRN
Dated: January 5, 2004
Received: January 7, 2004

Dear Mr. Rutkoskie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 04 0022

Device Name: *Stryker® Leibinger Universal Distal Radius System*

Indication For Use:

Stryker® Leibinger Universal Distal Radius System is intended for use in internal fixation of the small bone fractures, primarily including distal radius fractures. Examples of these distal radius fractures include but are not limited to compression fractures, intra-articular and extra-articular fractures, displaced fractures and surgical reduction. This system can be used for palmar, dorsal or orthogonal application.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040022

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)